

IAP7 Rec'd PCT/PTO 28 AUG 2006

PATENT

Docket No.: 20747/300 (ARDBW/P2990US)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	MILLAR, Robert Peter)
U. S. Serial No:	10/552,110)
PCT International Application No:	PCT/GB2004/001478)
Filed:	05 April 2004)
For :	GONADOTROPIN RELEASING)
	HORMONE ANALOGUES)
	CONJUGATES WITH STEROID)
	HORMONES)
)

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

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Dear Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. § 1.56, applicant hereby brings to the attention of the United States Patent and Trademark Office the enclosed documents listed on the attached PTO/SB/08 form.

Pursuant to 37 C.F.R. § 1.98(a)(2)(ii), copies of the cited U.S. Patents (i.e., Reference Cite Nos. 1-45) are not enclosed. Copies of all other listed references (i.e., Reference Cite Nos. 46-110) are enclosed herewith.

Pursuant to 37 CFR § 1.97(b)(3), no fee is required. Should it be determined that a fee is required, the Commissioner is authorized to charge any additional fee to Deposit Account No. 14-1138.

Respectfully submitted,

Date: August 25, 2006


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Substitute for form 1449A/PTO				<i>Complete if Known</i>	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Application Number	10/552,110
				Filing Date	April 5, 2004
				First Named Inventor	Robert Peter Millar
				Art Unit	To Be Assigned
				Examiner Name	To Be Assigned
Sheet	1	of	6	Attorney Docket Number	20747/300 (ARDBW/P2990US)

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	U.S. Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
1	US-3,813,382		05-28-1974	McKinley et al.	
2	US-3,843,065		10-22-1974	Horstman et al.	
3	US-3,849,389		11-19-1974	Shields	
4	US-3,855,199		12-17-1974	Foell et al.	
5	US-3,886,135		05-27-1975	McKinley et al.	
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11	US-3,915,947		10-28-1975	Shields	
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14	US-3,953,416		04-27-1976	Folkers et al.	
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23	US-4,072,668		02-07-1978	Amoss et al.	
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26	US-4,086,219		04-25-1978	Wittle et al.	
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36	US-4,677,193		06-30-1987	Rivier et al.	
37	US-4,705,778		11-10-1987	Almquist et al.	
38	US-5,064,939		11-12-1991	Rivier et al.	
39	US-5,371,070		12-06-1994	Koerber et al.	
40	US-5,413,990		05-09-1995	Haviv et al.	

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41	US-5,502,035		03-26-1996	Haviv et al.	
42	US-5,633,248		05-27-1997	Kato et al.	
43	US-5,756,497		05-26-1998	Bell et al.	
44	US-6,156,731		12-05-2000	Grass et al.	
45	US-6,191,115		02-20-2001	Haviv et al.	

FOREIGN PATENT DOCUMENTS					
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		Country Code ³ Number ⁴ Kind Code ⁵ (<i>if known</i>)			
46	WO 91/14704		10-03-1991	Applied Research Systems ARS Holding N.V.	
47	WO 93/03058		02-18-1993	University Technologies International Inc.	
48	WO 94/28015		12-08-1994	Biotech Australia Pty. Limited	
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53	WO 97/44041		11-27-1997	Merck & Co., Inc.	
54	WO 97/44321		11-27-1997	Merck & Co., Inc.	
55	WO 97/44339		11-27-1997	Merck & Co., Inc.	
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57	WO 98/55505		12-10-1998	Laboratoire Theramex	
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61	WO 99/41252		08-19-1999	Merck & Co., Inc.	
62	WO 99/46283		09-16-1999	Zealand Pharmaceuticals A/S	
63	WO 00/00493		01-06-2000	Takeda Chemical Industries, Ltd.	
64	WO 00/53178		09-14-2000	Merck & Co., Inc.	
65	WO 00/56739		09-28-2000	Takeda Chemical Industries, Ltd.	
66	WO 01/78780 A1		10-25-2001	Takeda Chemical Industries, Ltd.	X
67	WO 02/02533 A1		10-01-2002	Yamanouchi Pharmaceutical Co., Ltd.	X
68	WO 03/015820 A1		02-27-2003	Takeda Chemical Industries, Ltd.	X
69	EP 0 081 877 A1		06-22-1983	Coy et al.	
70	EP 0 192 492 A2		08-27-1986	The Salk Institute for Biological Studies	
71	GB 2 310 660 A		09-03-1997	Merck & Co., Inc.	

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				Filing Date	April 5, 2004
				First Named Inventor	Robert Peter Millar
				Group Art Unit	To Be Assigned
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OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T ²
	72	ALSENZ et al., "Oral Absorption of Peptides Through the Cobalamin (Vitamin B12) Pathway in the Rat Intestine," <i>Pharmaceutical Research</i> 17(7):825-832 (2000)		
	73	ANDERSON, "Hormonal Contraception in the Male," <i>British Medical Bulletin</i> 56(3):717-728 (2000)		
	74	ARÁNYI, "A Szteroid Hormonok Hatásainak Szerkezeti Alapjai," <i>Biológia</i> 30:145-169 (1982)		X
	75	ARÁNYI, "Dependence of Rate Constants of the Glucocorticoid Hormone-Receptor Interaction on Steroid Structure," <i>J. Steroid Biochem.</i> 17:137-141 (1982)		
	76	BURTON & WESTPHAL, "Steroid Hormone-Binding Proteins in Blood Plasma," <i>Metabolism</i> 21(3):253-276 (1972)		
	77	CHRISTIN-MAITRE et al., "Effect of Gonadotrophin-Releasing Hormone (GnRH) Antagonist During the LH Surge in Normal Women and During Controlled Ovarian Hyperstimulation," <i>Clin. Endocrinol.</i> 52:721-726 (2000)		
	78	CUNNINGHAM et al., "Steroid Structural Requirements for High Affinity Binding to Human Sex Steroid Binding Protein (SBP)," <i>Steroids</i> 38(3):243-262 (1981)		
	79	DANFORTH et al., "Intermittent GNRH Antagonist Plus Progestin Contraception Conserving Tonic Ovarian Estrogen Secretion and Reducing Progestin Exposure," <i>Contraception</i> 41(6):623-631 (1990)		
	80	DITKOFF et al., "The Gonadotropin-Releasing Hormone Antagonist (Nal-Glu) Acutely Blocks the Luteinizing Hormone Surge but Allows for Resumption of Folliculogenesis in Normal Women," <i>Am. J. Obstet. Gynecol.</i> 165(6 Pt 1):1811-1817 (1991)		
	81	DUAX & GRIFFIN, "Molecular Structure, Receptor Binding and Activity of Sex Steroids," <i>Frontiers in Drug Research</i> , Alfred Benzon Symposium, 28:62-74 (1990)		
	82	DUAX & GRIFFIN, "Steroid Hormone Structure, Receptor Binding and Activity: Empirical Drug Design," <i>Structure-Based Drug Design</i> , P.W. Codding (ed.), pp.1-14 (1998)		
	83	DUAX & GRIFFIN, "The Structure and Receptor Binding of Steroid Hormones," <i>Advances in Drug Research</i> 18:115-138 (1989)		

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	84	DUNCAN et al., "A New Reagent Which May Be Used to Introduce Sulfhydryl Groups into Proteins, and Its Use in the Preparation of Conjugates for Immunoassay," <i>Anal. Biochem.</i> 132:68-73 (1983)		T ²
	85	DUTTA & FURR, "Luteinizing Hormone Releasing Hormone (LHRH) Analogs," <i>Annual Reports in Medicinal Chemistry-20</i> , Chapter 21, pp.203-214 (1985)		
	86	FRASER et al., "Effect of Late Follicular Phase Administration of Antide on Ovulation and Inhibin Secretion in Macaques," <i>Contraception</i> 44(6):667-676 (1991)		
	87	FRASER et al., "Suppression of Luteal Function by a Luteinizing Hormone-Releasing Hormone Antagonist During the Early Luteal Phase in the Stumptailed Macaque Monkey and the Effects of Subsequent Administration of Human Chorionic Gonadotropin," <i>Endocrinology</i> 121(2):612-618 (1987)		
	88	GOULET, "Gonadotropin Releasing Hormone Antagonists," <i>Annual Reports in Medicinal Chemistry-30</i> , Chapter 18, pp.169-178 (1995)		
	89	KENIGSBERG & HODGEN, "Ovulation Inhibition by Administration of Weekly Gonadotropin-Releasing Hormone Antagonist," <i>J. Clin. Endocrinol. Metabol.</i> 62(4):734-738 (1986)		
	90	KLOSTERMAN et al., "Cortisol Levels, Binding, and Properties of Corticosteroid-Binding Globulin in the Serum of Primates," <i>Endocrinology</i> 118(1):424-434 (1986)		
	91	LU et al., "Improved Synthesis of 4-Alkoxybenzyl Alcohol Resin," <i>J. Org. Chem.</i> 46:3433-3436 (1981)		
	92	MATTOX et al., "A Comparison of Procedures for Attaching Steroidal Glucosiduronic Acids to Bovine Serum Albumin," <i>J. Steroid Biochem.</i> 10:167-172 (1979)		
	93	MCEWAN et al., "Synthesis and Biological Activity of Ribose-5'-Carbamate Derivatives of Vitamin B ₁₂ ," <i>Bioconjugate Chem.</i> 10:1131-1136 (1999)		
	94	MICKELSON et al., "Steroid-Protein Interactions. Human Corticosteroid Binding Globulin: Some Physicochemical Properties and Binding Specificity," <i>Biochemistry</i> 20:6211-6218 (1981)		
	95	MILLAR et al., "GnRH and GnRH Analogs: Structure, Actions and Clinical Applications," <i>Hormone Frontier in Gynecology</i> 5(4):77-83 (1998)		

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	96	MILLAR et al., "Progress Towards the Development of Non-Peptide Orally-Active Gonadotropin-Releasing Hormone (GnRH) Antagonists: Therapeutic Implications," <i>British Medical Bulletin</i> 56(3):761-772 (2000)		
	97	MILLAR, "Gonadotropin-Releasing Hormones and Their Receptors," <i>Reproductive Medicine: Molecular, Cellular and Genetic Fundamentals</i> , Bart C.J.M. Fauser (Ed.), The Parthenon Publishing Group, New York, Chapter 1, pp.199-223 (2003)		
	98	NESTOR, JR., "Luteinizing Hormone Releasing Hormone Analogs in Control of Fertility and Gonadal Hormone Dependent Disease," <i>Annual Reports in Medicinal Chemistry-23</i> , Chapter 22, pp.211-220 (1988)		
	99	NESTOR, JR., "Potent Gonadotropin Releasing Hormone Antagonists with Low Histamine-Releasing Activity," <i>J. Med. Chem.</i> 35:3942-3948 (1992)		
	100	O'SULLIVAN et al., "Comparison of Two Methods of Preparing Enzyme-Antibody Conjugates: Application of These Conjugates for Enzyme Immunoassay," <i>Analytical Biochemistry</i> 100:100-108 (1979)		
	101	OJASOO et al., "Two Approaches to Structure-Activity Relationships in the Field of Sex-Steroids and Their Analogs," <i>Molecular Structure and Biological Activity of Steroids</i> , Chapter 4, pp.157-207 (1992)		
	102	PAVLOU et al., "Combined Administration of a Gonadotropin-Releasing Hormone Antagonist and Testosterone in Men Induces Reversible Azoospermia without Loss of Libido," <i>J. Clin. Endocrinol. Metabol.</i> 73(6):1360-1369 (1991)		
.	103	RAHIMIPOUR et al., "Design, Synthesis, and Evaluation of a Long-Acting, Potent Analogue of Gonadotropin-Releasing Hormone," <i>J. Med. Chem.</i> 44:3645-3652 (2001)		
	104	RAYNAUD & OJASOO, "The Relevance of Structure-Affinity Relationships in the Study of Steroid Hormone Action," <i>Steroid Hormone Receptors: Structure and Function</i> , Elsevier Science Publishers B.V., H. Eriksson & J.-A. Gustafsson (Ed.), pp.141-170 (1983)		
	105	RUSSELL-JONES et al., "Synthesis of LHRH Antagonists Suitable for Oral Administration via the Vitamin B ₁₂ Uptake System," <i>Bioconjugate Chem.</i> 6:34-42 (1995)		
	106	SEAL & DOE, "Vertebrate Distribution of Corticosteroid-Binding Globulin and Some Endocrine Effects on Concentration," <i>Steroids</i> 5:827-841 (1965)		

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